

# UTILITY PATENT APPLICATION TRANSMITTAL

## (Large Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.  
58267-CON2(46453)

Total Pages in this Submission

Forty-three

### TO THE COMMISSIONER FOR PATENTS

Mail Stop Patent Application  
P.O. Box 1450  
Alexandria, VA 22313-1450

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

LOW DOSE ESTROGEN INTERRUPTED HORMONE REPLACEMENT THERAPY

and invented by:

ROBERT F. CASPER, GARY A. SHANGOLD, AND MILITZA K. AUSMANAS

If a **CONTINUATION APPLICATION**, check appropriate box and supply the requisite information:

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 10/134,455

Which is a:

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 09/538,485

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: \_\_\_\_\_

Enclosed are:

### Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 24 pages and including the following:
  - a. ☒ Descriptive Title of the Invention
  - b. ☒ Cross References to Related Applications (if applicable)
  - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
  - d. ☐ Reference to Sequence Listing, a Table, or a Computer Program Listing Appendix
  - e. ☒ Background of the Invention
  - f. ☒ Brief Summary of the Invention
  - g. ☒ Brief Description of the Drawings (if filed)
  - h. ☒ Detailed Description
  - i. ☒ Claim(s) as Classified Below
  - j. ☒ Abstract of the Disclosure

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**Application Elements (Continued)**

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
- a. ☒ Formal                      Number of Sheets ONE (1)
- b. ☐ Informal                      Number of Sheets \_\_\_\_\_
4. ☒ Oath or Declaration
- a. ☐ Newly executed *(original or copy)*                      ☐ Unexecuted
- b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
- c. ☒ With Power of Attorney                      ☐ Without Power of Attorney
- d. ☐ DELETION OF INVENTOR(S)  
Signed statement attached deleting inventor(s) named in the prior application,  
see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*  
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under  
Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby  
incorporated by reference therein.
6. ☐ CD ROM or CD-R in duplicate, large table or Computer Program (Appendix)
7. ☐ Application Data Sheet (See 37 CFR 1.76)
8. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*
- a. ☐ Computer Readable Form (CRF)
- b. ☐ Specification Sequence Listing on:
- i. ☐ CD-ROM or CD-R (2 copies); or
- ii. ☐ Paper
- c. ☐ Statement(s) Verifying Identical Paper and Computer Readable Copy

**Accompanying Application Parts**

9. ☐ Assignment Papers *(cover sheet & document(s))*
10. ☐ 37 CFR 3.73(B) Statement *(when there is an assignee)*
11. ☐ English Translation Document *(if applicable)*
12. ☒ Information Disclosure Statement/PTO-1449                      ☐ Copies of IDS Citations
13. ☒ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☒ Certificate of Mailing
- ☐ First Class                      ☒ Express Mail *(Specify Label No.):* EV438991345US

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**Accompanying Application Parts (Continued)**

17. ☒ Additional Enclosures *(please identify below)*:

PATENT APPLICATION TITLE PAGE.

**Request That Application Not Be Published Pursuant To 35 U.S.C. 122(b)(2)**

18. ☐ Pursuant to 35 U.S.C. 122(b)(2), Applicant hereby requests that this patent application not be published pursuant to 35 U.S.C. 122(b)(1). Applicant hereby certifies that the invention disclosed in this application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing of the application.

**Warning**

***An applicant who makes a request not to publish, but who subsequently files in a foreign country or under a multilateral international agreement specified in 35 U.S.C. 122(b)(2)(B)(i), must notify the Director of such filing not later than 45 days after the date of the filing of such foreign or international application. A failure of the applicant to provide such notice within the prescribed period shall result in the application being regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional.***

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**Fee Calculation and Transmittal**

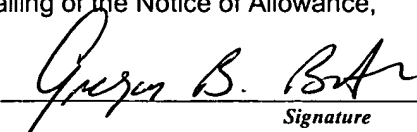
**CLAIMS AS FILED**

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	10	- 20 =	0	x \$18.00	\$0.00
Indep. Claims	1	- 3 =	0	x \$86.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$770.00
OTHER FEE (specify purpose) _____					\$0.00
TOTAL FILING FEE					\$770.00

- ☒ A check in the amount of **\$770.00** to cover the filing fee is enclosed.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **04-1105** as described below.
- ☐ Charge the amount of \_\_\_\_\_ as filing fee.
  - ☒ Credit any overpayment.
  - ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
  - ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **MARCH 22, 2004**

cc:

  
Signature  
**GREGORY B. BUTLER, Ph.D., ESQ.**  
REG. NO.: 34,558  
EDWARDS & ANGELL, LLP  
P.O. BOX 55874  
BOSTON, MA 02205  
TEL.: 617-439-4444  
FAX: 617-439-4170  
CUSTOMER NO.: 21874

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**Applicant(s): **ROBERT F. CASPER, ET AL.**

Docket No.

**58267-CON2(46453)**

Serial No.

-

Filing Date

**HEREWITH**

Examiner

**B. BADIO (PRESUMED)**

Group Art Unit

**1616 (PRESUMED)**Invention: **LOW DOSE ESTROGEN INTERRUPTED HORMONE REPLACEMENT THERAPY**

I hereby certify that the following correspondence:

**NEW CONTINUATION PATENT APPLICATION AND RELATED PAPERS.***(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

**MARCH 22, 2004***(Date)***DONNA R. DAVIS***(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)***EV438991345US***("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.****EV438991345US**